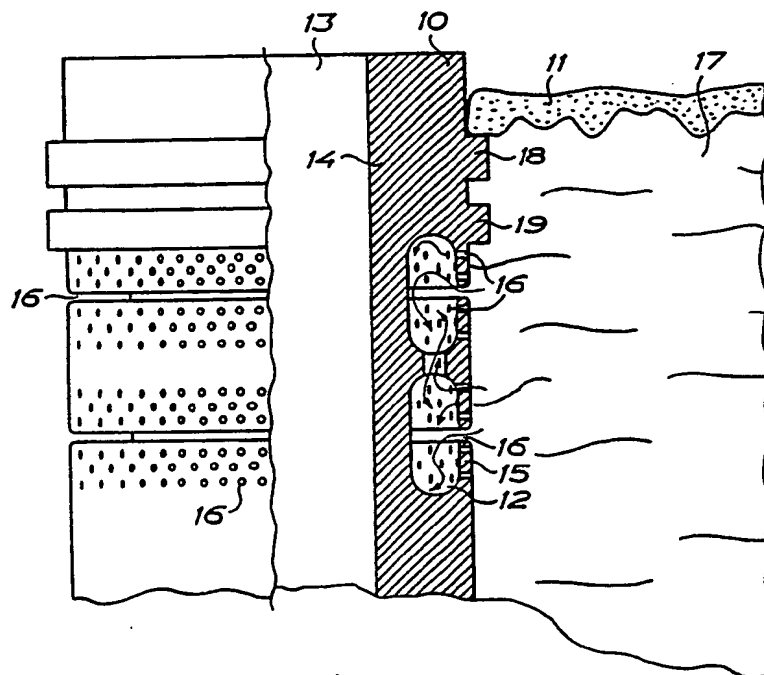




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(54) Title: ELEMENT FOR CONTROLLED GROWTH INTO SURGICALLY INTERVENED AREAS



(57) Abstract

An element for control growth of tissue into surgically intervened areas, e.g. for passages through skin or mucous membrane, or for controlled growth of tissue around surgically treated teeth which have lost part of the supporting tissue thereof, forms one or more undercut cavities (12) which are each available through one or more openings (16) on the outside of the element. The surfaces of the element which are exposed to surrounding tissue consist of or are coated with a biocompatible material.

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ELEMENT FOR CONTROLLED GROWTH INTO SURGICALLY INTERVENED AREAS

The invention relates to an element for controlled
5 growth of tissue into surgically intervened areas, e.g.
for passages through skin or mucous membrane. An element
may be concerned which is used for attaching a
prosthesis in the body or which forms per se such a
prosthesis. In a modified embodiment, the element can
10 also be utilized for controlled regeneration of
supporting tissue around teeth, which has been lost.

When an element is to be incorporated into a tissue
or is to be implanted in such a way that it must pass
through several tissues as the case is inter alia when a
15 passage has to be made through the skin or through a
mucous membrane, it is required that the element is
biocompatible, i.e. the element must be accepted by the
tissue, and the problem arises to provide a safe
retension of the element in the surrounding tissue so
20 that the element will not be dislocated mechanically. An
unsatisfactory biocompatibility as well as an
insufficient retension causes irritation of the tissues
and possibly tissue rupture as a consequence thereof in
connection with the element. This means that reactive
25 zones of connective tissue with a more or less
significant strain of inflammation are formed, which
results in the element no longer being maintained
harmonically incorporated into the tissue region. The
element starts to drift and to lose its function. As far
30 as passages through skin or mucous tissue are concerned,
the tissue irritation moreover results in epithelium
growing down around the element with repellation as the
final consequence thereof. When lost supporting tissue
is regenerated around teeth, it is moreover necessary to
35 control in a specific order the growth of the specific

tissues which form attachment for the tooth, into the element.

In order to solve these problems the element of the invention has obtained the characteristics appearing
5 from claim 1.

In order to explain the invention in more detail reference is made to the accompanying drawings in which
FIG. 1 is a diagrammatic sectional view
illustrating an implanted element which extends
10 through the outer skin, and
FIG. 2 is a diagrammatic sectional view
illustrating a modified element for regeneration of lost supporting tissue around teeth.

In FIG. 1, an implanted element 10 of the invention
15 is shown, which extends through the outer skin the outermost cellular layer, the epithelium, of which is shown at 11.

In the embodiment shown herein, the element is tubular and can comprise e.g. an implanted conduit for
20 performing peritoneal dialysis. The conduit can be rigid or flexible. It forms a number of cavities 12 which are defined towards the passage 13 through the element by a solid wall 14. Towards the outside surface of the element the cavities are defined by a perforated wall 15
25 the perforations of which are indicated at 15 and comprise circular openings as well as circumferential slots. The connective tissue which is indicated at 17, grows into the cavities 12, matures and attains a structural organization which prevents the epithelium 11
30 from growing downwards along the surface of the element and from infiltrating the layer of connective tissue adjacent the element and thus preventing the epithelium from enclosing the element 10, which would result in repellation of the element. The growth of the connective
35 tissue into the cavities should be such that the

connective tissue inside the cavities will be complete and will be fully matured, i.e. the slots 16 should be sufficiently large so as to allow the cells of the connective tissue as well as the blood vessels necessary for the supply to the connective tissue, to grow into the cavities and thus to create such conditions that the cells of the connective tissue can produce fibers of such tissue and matrix and that the components of the connective tissue can mature and be renewed in a normal way.

Taking these conditions into consideration, it is proposed according to the invention to arrange the openings 16 with a minimum dimension of 30 μ m. The depth of the cavities 12, i.e. the distance between the walls 14 and 15, also should have a minimum size of 30 μ m.

According to the invention, the element 10 on the surfaces which are exposed to the surrounding tissue, comprises a biocompatible material, and an excellent material of this type is titanium. The element in its entirety can consist of titanium, but it is preferred that the element on said surfaces; i.e. on the outside surface thereof, in the openings 16 and in the cavities 12 is coated with titanium by a thin layer thereof being deposited on a supporting body by evaporation in vacuum. This supporting body can be rigid or flexible and can be made e.g. of silicon rubber, polyester, or polytetrafluoro ethylene. In the embodiment shown, openings 16 are formed with sharp edges, but the edges can be made in another way e.g. with a chamfer on the outside surface of the element or inside the cavities 12, or they can be curved.

When an element for passage through skin or mucous membrane is implanted in the body tissue in the manner described, the connective tissue is allowed to mature adjacent the surface of the element and inside the

cavities in order to achieve a reliable and permanent retention of the element while the epithelium is prevented from growing down around the element at the passage through the skin or the mucous membrane.

5 If the element surfaces which are exposed to the surrounding soft tissue, are given a surface topography in the shape of grooves extending in parallel with each other and having a predetermined minimum depth and walls which are so steep that they form significant angles
10 between the bottom of the groove, the walls thereof and the portion between two grooves, the drift of epithelium cells along said surface can be prevented or alternatively greatly retarded in a direction
15 perpendicular to the extension of the grooves when elements forming passages through skin or mucous membrane are implanted.

 The region of the element surface immediately above the uppermost opening in the perforated wall of the element, which is exposed to the epithelium layer,
20 therefore is given a suitable profile, and this region e.g. can form circumferential ribs 18 and 19 according to FIG. 1. This arrangement provides a supplementary protection against growth of epithelium downwards along the surface of the element for the period necessary for
25 the granulation tissue of the wound region to mature to a firm structured connective tissue.

 When elements adapted for the penetration of skin or mucous membrane in regions requiring a longer healing period so as to provide for the connective tissue
30 sufficient possibilities of maturing, are being implanted, the surgical operation preferably is performed in two stages. Stage 1 is a surgical operation with total implantation of the element including a tube closure, if any, in soft or hard tissue. After a period
35 adjusted individually, stage 2 is performed wherein a

desired portion of the element is exposed for connection to a tissue or organ-external system.

When lost supporting tissue around teeth is to be regenerated, a modified element 10' according to FIG. 2 is utilized. This element principally is formed as the wall of the tubular element previously described, but there is the difference that the wall in this case is double with the openings 16 facing two directions. The intermediate wall 20 can be a solid or perforated wall with passages 21 causing retarded growth due to a corrugated labyrinthine course of the cells forming connective tissue and bone, which are more rapidly regenerating than the root membrane cells forming root cement. These passages can also be made more directly penetrating but in that case should be filled with resorptive material so as to retard the growth of the more rapid cells. After an individually adjusted surgical operation the element is put into contact with the root surface 22 which should be made the object of regeneration of lost supporting tissue. On the tooth side of the element, root membrane cells and blood vessels are allowed to grow into the element from remaining root membrane. On the other side cells of connective tissue (and bone cells) as well as vessels from the connective tissue and bone tissue regions are allowed to grow into the element. It is presumed that the tissue that has grown into the element matures in the manner previously discussed. On the tooth side, root membrane tissue with root cement and root membrane fibers adhering thereto will be formed. On the other side connective tissue and bone will mature.

If the intermediate wall 20 is solid, the coupling between the root membrane and the surrounding tissue will take place mechanically via the double side perforation of the element. When the intermediate wall

is perforated, the coupling also will take place directly via the several tissue components from the two sides.

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CLAIMS

1. Element for controlled growth of tissue into surgically intervened areas, e.g. for passages through skin or mucous membrane, or for controlled growth of tissue around teeth for regeneration of supporting tissue that has been lost, c h a r a c t e r i z e d in that the element (10) forms one or more undercut cavities (12) which are each available through one or more openings (16) on the outside of the element, and that the surfaces of the element, which are exposed to surrounding tissue, consist of or are coated with a biocompatible material.

2. Element as claimed in claim 1, c h a r a c t e r i z e d in that the biocompatible material comprises titanium.

3. Element as claimed in claim 2, c h a r a c t e r i z e d in that the titanium is deposited by evaporation in vacuum on a rigid or flexible support body.

4. Element as claimed in any of claims 1 to 3, c h a r a c t e r i z e d in that the cavity (12) is defined by a perforated outer wall (15).

5. Element as claimed in any of claims 1 to 4, c h a r a c t e r i z e d in that the openings (16) have a minimum dimension of 30 μm .

6. Element as claimed in any of claims 1 to 5, c h a r a c t e r i z e d in that the cavity has a minimum depth of 30 μm .

7. Element as claimed in any of claims 1 to 6, c h a r a c t e r i z e d in that the element (10') is tubular with the cavities (12) available through openings in the outer as well as the inner curved surface.

8. Element as claimed in claim 7, c h a r a c t e r i z e d in that the cavities (12)

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which are available through openings (16) in the outer curved surface, and cavities which are available through openings (16) in the inner curved surface, are separated by a solid or perforated wall (20).

- 5 9. Element as claimed in any of claims 1 to 8, characterized in that the element (10, 10') adjacent the outermost cavity (12) is profiled externally, e.g. provided with ribs (18, 19).

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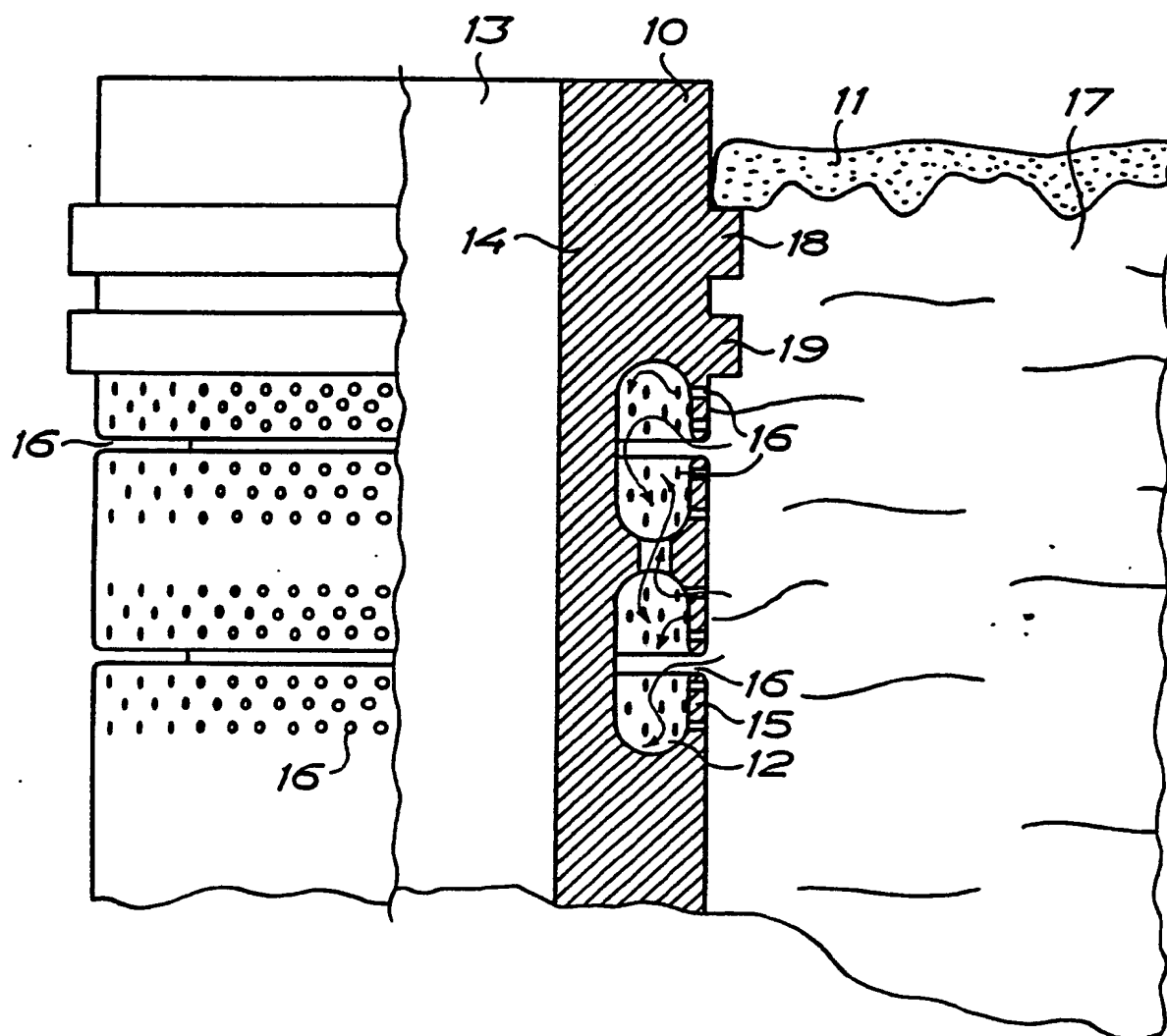


FIG. 1

SUBSTITUTE SHEET

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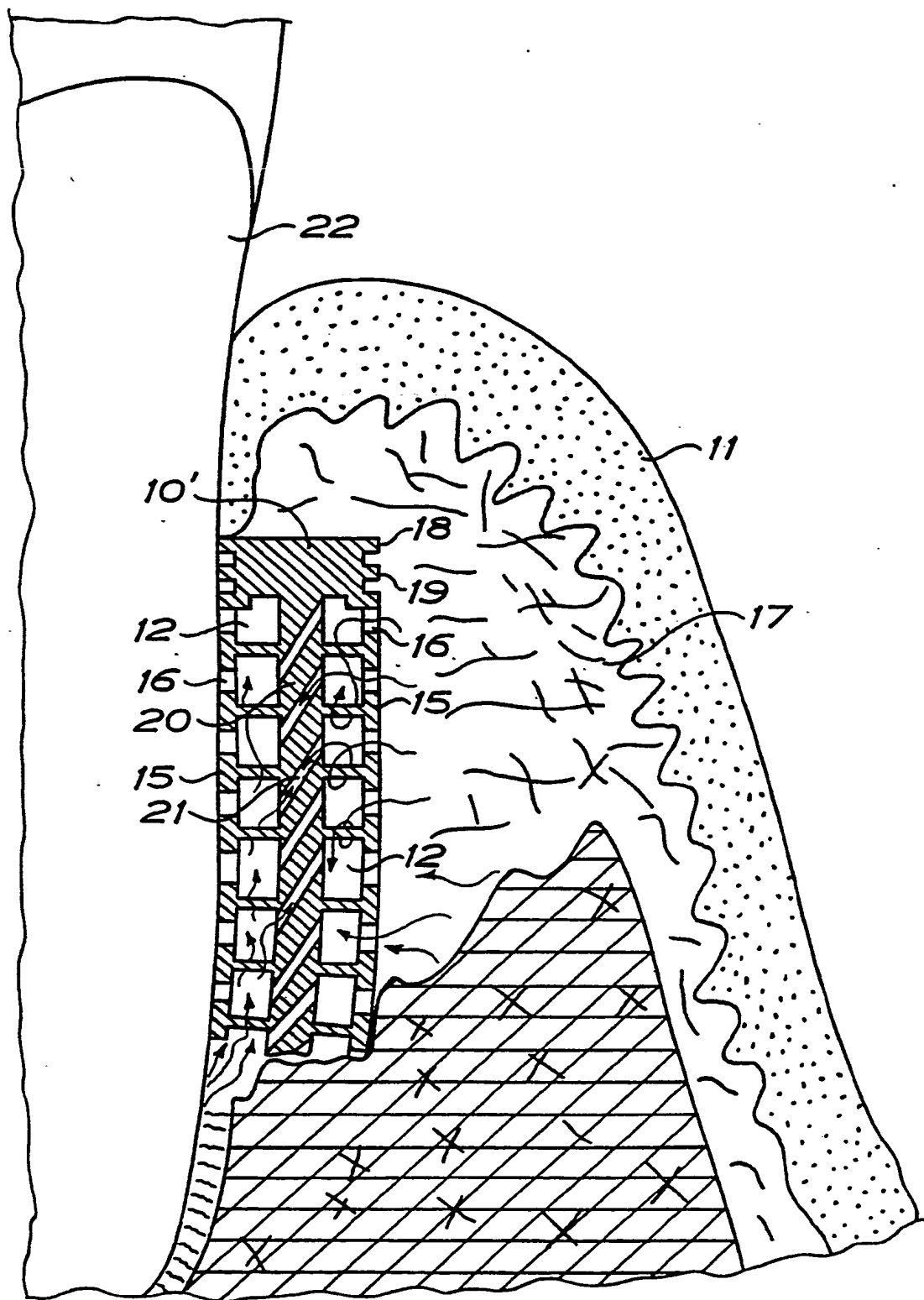



FIG. 2

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE85/00091

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC 4		
A 61 F 2/02, A 61 C 8/00, A 61 L 27/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC 3, 4	A 61 F 1/00,04, 2/00,02	
US C1	3:1, 1.9, 1.91, 1.912	
Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched *		
SE, NO, DK, FI classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, 11 with indication, where appropriate, of the relevant passages 12	Relevant to Claim No. 13
A	SE, B, 7504625-0 (P-I BRÄNEMARK ET AL) 11 September 1978	1, 4, 7-9
P	DE, A, 3 416 471 (O FREY) 10 January 1985	1, 4
A	GB, A, 2 005 546 (P NIEDERER) 25 April 1979	1, 4, 9
A	WO, A1, 81/02668 (J SCALES) 1 October 1981	1-8
X	US, A, 3 700 380 (S KITRILAKIS) 24 October 1972 & NL, 7113418 FR, 2109931 DE, 2149027 GB, 1347791 CH, 551185 CA, 940451 SE, 383475	1-8
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
1985-06-13		1985-06-14
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